

### **REMARKS**

It is not believed that this response occasions any fee, but should there be any fee, please charge same to Deposit Account No. 10-9750/MCP0274/TT.

Claim 16 is amended to provide the term "a particle."

It is submitted that no new matter has been added by the above amendments.

Claims 1-20 are currently pending in the captioned application.

### **Indefiniteness Rejection**

Claim 16 was rejected under 35 USC §112, second paragraph. (Part of Paper No./ Mail Date 05242005 at 2.) In making the rejection, the Examiner asserted that Claim 16 recites the limitation "the particle" in line 1 and that claim 1 does not recite particle size. Therefore, the Examiner concluded that there is insufficient antecedent basis for this limitation in the claim (*Id.*).

Claim 16 has been amended in view of the Examiner's position concerning the lack of the explicit word "particle" in claim 1. It is believed that this ground of rejection is now moot and should be withdrawn.

### **Anticipation Rejections**

Claims 1, 3-6, 10, and 17-19 were rejected under 35 USC §102(b) as anticipated by Harbit, US Patent No. 3,108,046 ("Harbit"). (Part of Paper No./ Mail Date 05242005 at 3.)

For the reasons set forth below, the rejection, respectfully is traversed.

Harbit discloses

This invention relates to the method of making a high dosage sustained release orally administrable tablet and to the product of this method. More particularly, this invention provides a versatile, simplified method of preparing sustained release tablets with a high degree of control of the rate of drug release. 15

5 10 15 20 25 30 35 40 45 50 55 60 65 70 75 80 85 90 95 100 105 110 115 120 125 130 135 140 145 150 155 160 165 170 175 180 185 190 195 200 205 210 215 220 225 230 235 240 245 250 255 260 265 270 275 280 285 290 295 300 305 310 315 320 325 330 335 340 345 350 355 360 365 370 375 380 385 390 395 400 405 410 415 420 425 430 435 440 445 450 455 460 465 470 475 480 485 490 495 500 505 510 515 520 525 530 535 540 545 550 555 560 565 570 575 580 585 590 595 600 605 610 615 620 625 630 635 640 645 650 655 660 665 670 675 680 685 690 695 700 705 710 715 720 725 730 735 740 745 750 755 760 765 770 775 780 785 790 795 800 805 810 815 820 825 830 835 840 845 850 855 860 865 870 875 880 885 890 895 900 905 910 915 920 925 930 935 940 945 950 955 960 965 970 975 980 985 990 995 1000 1005 1010 1015 1020 1025 1030 1035 1040 1045 1050 1055 1060 1065 1070 1075 1080 1085 1090 1095 1100 1105 1110 1115 1120 1125 1130 1135 1140 1145 1150 1155 1160 1165 1170 1175 1180 1185 1190 1195 1200 1205 1210 1215 1220 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In accordance with this invention the time delay material is a lipid material which is solid at room temperature, but has a low melting point of from 40° C. to 150° C. preferably 60° C. to 110° C. and is also non-toxic and pharmaceutically acceptable. 15

The time delay material is a substantially water insoluble material resistant to disintegration in the gastrointestinal tract and providing for a gradual release of the medicament in said tract. The time delay material may be, for example, a wax, a fatty acid, alcohol or ester, alone, or an admixture thereof. 20

The wax may be paraffin wax; a petrolatum wax; a mineral wax such as ozokerite, ceresin, utah wax or montan wax; a vegetable wax such as, for example, carnauba wax, Japan wax, bayberry wax, flax wax; an animal wax such as, for example, spermaceti; or an insect wax such as beeswax, Chinese wax or shellac wax. 25 30 Col. 3.

In making the rejection, the Examiner contended only that:

Harbit discloses a high dose tablet comprising from about 75% to about 98% drug and wax, such as paraffin wax or shellac wax (column 3, lines 1-31). The tablet dosage further comprises lubricant (column 4, lines 9-19). The dosage form provides both immediate release and sustained release (column 4, lines 21-31).

Part of Paper No./ Mail Date 05242005 at 3.)

As is well settled, anticipation requires "identity of invention." Each and every element recited in a claim must be found in a single prior art reference and arranged as in the claim.

Furthermore, in a §102(b) rejection there must be no difference between what is claimed and what is disclosed in the applied reference. Moreover, it is incumbent upon the Examiner to *identify wherein each and every facet* of the claimed invention is disclosed in the applied reference." The Examiner is required to point to the disclosure in the reference "*by page and line*" upon which the claim allegedly reads.

The rejection fails to identify where in Harbit each and every element of the rejection claims is shown. For example, the rejection fails to state where the affirmatively required "powdered wax" is disclosed. That was the Examiner's burden. Because the Examiner failed to satisfy that burden the rejection is improper should be withdrawn.

As to claim 5 the Examiner failed to state where the affirmatively required disclosure of a “tablet [that] is substantially free of water-soluble, non-saccharide polymeric binders” is to be found in Harbit. That was the Examiner’s burden. Because the Examiner failed to satisfy that burden the rejection is improper should be withdrawn.

As to claim 6 the Examiner failed to state where the affirmatively required disclosure of a “tablet [that] is substantially free of hydrated polymers” is to be found in Harbit. That was the Examiner’s burden. Because the Examiner failed to satisfy that burden the rejection is improper should be withdrawn.

As to claim 18, the Examiner failed to state where the affirmatively required disclosure of a “tablet [that] is substantially free of water-soluble, non-saccharide polymeric binders” is to be found in Harbit. That was the Examiner’s burden. Because the Examiner failed to satisfy that burden the rejection is improper should be withdrawn.

As to claim 19, the Examiner failed to state where the affirmatively required disclosure of a “tablet [that] is substantially free of hydrated polymers” is to be found in Harbit. That was the Examiner’s burden. Because the Examiner failed to satisfy that burden the rejection is improper should be withdrawn.

As to claim 20, the Examiner failed to state where the affirmatively required disclosure of an “active ingredient is in its native crystalline form” is to be found in Harbit. That was the Examiner’s burden. Because the Examiner failed to satisfy that burden the rejection is improper should be withdrawn.

Even further, the rejection does not point out where there is a disclosure of the required powdered wax in a swallowable immediate release tablet and a swallowable immediate release tablet meeting the USP dissolution specifications for immediate release tablets containing said active ingredient. Nor is it believed that the Examiner could make such a showing because Harbit discloses using wax in a controlled release formulation, not in an immediate release formulation. For this additional reason, the rejection is improper and should be withdrawn.

Claims 1 and 4-10 were rejected under 35 USC §102(b) as anticipated by Cheng, US Patent No. 6,099,859 (“Cheng”). (Part of Paper No./ Mail Date 05242005 at 4.)

For the reasons set forth below, the rejection, respectfully is traversed.  
Cheng discloses